REMARKS

General

Claims 49-52, 55, 71-73, 76, 80, 84, 166-172, 176-181, and 217-220 are pending in the present application. In this response, claims 49, 76, 80, and 84 have been amended. Exemplary support for the claim amendments and new dependent claims can be found throughout the application as originally filed. See, for example, page 66, lines 1-13 and page 67, lines 1-20 of the present specification.

Applicants respectfully request the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and the following remarks.

Rejection under 35 U.S.C. § 102

Claims 49-52, 55, 166, 168, 172, and 218 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated over Bendayan, *Double Immunocytochemical Labeling Applying the Protein A-Gold Technique*, J. Histochemistry and Cytochemistry, 30(1): 81-85 (1982) (hereinafter "Bendayan"). This rejection is respectfully traversed.

Legal Standard

It should be noted that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). It should further be noted that unless a reference discloses within the four corners of the document not only all of the limitations claimed but also all of the limitations arranged or combined in the same

way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 USC 102. Net Moneyin, Inc. v. Verisign, Inc., 545 F.3d 1359, 88 U.S.P.Q.2d 1751 (Fed. Cir. Oct. 20, 2008).

Pending Claims

Independent claim 49 is the only independent claim pending in the present application. Rejected claims 50-52, 55, 166, 168, 172, and 218 depend from claim 49. Claim 49 recites a population of scattered light-detectable gold particles. The gold particles of claim 49 have a diameter of from about 40 nm to about 140 nm.

Cited References

Bendayan discusses monodispersed colloidal gold suspensions with particles of 190 ± 5 Å (i.e., 19.0 ± 0.5 nm) in diameter. (Page 82, Col. 2).

Differences between Pending Claims and Cited References

While Bendayan discusses gold particles having diameters of 19.0 ± 0.5 nm (*i.e.*, 190 ± 5 Å), it should be noted that claim 49 recites gold particles having a diameter of from about 40 nm to about 140 nm.

Accordingly, Bendayan fails to disclose or suggest gold particles having a diameter of from about 40 nm to about 140 nm, as presently recited in claim 49.

In view of at least the foregoing, Bendayan fails to disclose or suggest all the features recited in claim 49.

Thus, claim 49 is not anticipated by Bendayan. As rejected claims 50-52, 55, 166, 168, 172, and 218 depend either directly or indirectly from claim 49, the foregoing rejected dependent claims are not anticipated by Bendayan for at least the same reasons discussed hereinabove.

Rejections under 35 U.S.C. § 103

Claims 49-52, 55, 76, 166-172, 176-179, 217, and 218 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 4,647,544 (hereinafter "Nicoli") in view of Bendayan. Claims 71-72 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nicoli in view of Bendayan and further in view of U.S. Patent No. 4,929,400 (hereinafter "Rembaum"). Claims 71-72 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bendayan in view of Rembaum. Claims 73, 80, and 84 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nicoli in view of Bendayan and further in view of Rembaum and U.S. Patent No. 5,552,086 (hereinafter "Siiman"). Claims 73, 80, and 84 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bendayan in view of Rembaum and in view of Siiman. Claims 180 and 181 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Nicoli in view of Bendayan and further in view of U.S. Patent No. 5,567,628 (hereinafter "Tarcha"). Claims 180 and 181 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Bendayan in view of Tarcha. These rejections are respectfully traversed.

Legal Standard

The Office has the initial burden of establishing a factual basis to support the legal conclusion of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). For rejections under 35 U.S.C. § 103(a) based upon a combination of prior art elements, in KSR Int'l v. Teleflex Inc., 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007), the Supreme Court stated that a patent composed of several elements is not proved obvious merely by demonstrating that each of its

elements was, independently, known in the prior art. Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

Pending Claims

Independent claim 49 is the only independent claim pending in the present application. Rejected claims 50-52, 55, 76, 166-172, 176-179, 217, and 218 depend from claim 49. Claim 49 recites a population of scattered light-detectable gold particles. The gold particles of claim 49 have a diameter of from about 40 nm to about 140 nm and have less than a 5% coefficient of variation in size. The population of gold particles in claim 49 excludes polystyrene particles.

Cited References

Bendayan and Nicoli have been relied upon in multiple rejections as primary references.

As discussed hereinabove, Bendayan discusses gold particles having diameters of 19.0 $\pm$ 0.5 nm (*i.e.*, 190 $\pm$ 5 Å).

The Examiner's position is that Nicoli discusses "colloidal gold particles which have been coated with a variety of macromolecules such as avidin, lectins, IgG in the size range of 20 to 500 nm (column 15, lines 25-35)." (Office Action, Page 4). The Examiner concedes that Nicoli fails "to teach that the coefficient of variation in size of the population of particles is less than 5%". (Office Action, Page 4).

Differences between Pending Claims and Cited References

As discussed hereinabove, while Bendayan discusses gold particles having diameters of 19.0 ± 0.5 nm (*i.e.*, 190 ± 5 Å), claim 49 recites gold particles having a diameter of from about 40 nm to about 140 nm. Accordingly, Bendayan fails to disclose or suggest gold particles having a diameter of from about 40 nm to about 140 nm, as presently recited in claim 49.

As conceded by the Examiner, Nicoli does not disclose or suggest gold particles having less than a 5% coefficient of variation in size. While Bendayan discusses gold particles having average diameters of 19.0 ± 0.5 nm based on an evaluation of 100 particles (Page 82, Col. 2), the present specification clearly defines that "percent coefficient of variation is defined as the standard deviation of the particle size distribution divided by the mean of the particle preparation." (Page 85, lines 30-33 of the present specification). Bendayan does not disclose or suggest the standard deviation of the particle size distribution in order to determine the percent coefficient of variation in particle size. Thus, Bendayan does not disclose or suggest a less than 5% coefficient of variation in size, as recited in claim 49.

Accordingly, Bendayan and Nicoli, either alone or in combination, do not disclose or suggest gold particles having a diameter of from about 40 nm to about 140 nm and having less than a 5% coefficient of variation in size, as recited in claim 49.

The Examiner has relied upon Rembaum, Siiman, and Tarcha as secondary references in multiple rejections. These secondary references fail to cure at least the above-noted deficiencies of Bendayan and Nicoli.

In view of at least the above, the cited references fail to disclose or suggest all the features recited in claim 49.

Thus, a *prima facie* case of obviousness of claim 49 has not been established. As claims 50-52, 55, 76, 166-172, 176-179, 217, and 218 depend either directly or indirectly from claim 49, a *prima facie* case of obviousness of 50-52, 55, 76, 166-172, 176-179, 217, and 218 has not been established for at least the same reasons discussed hereinabove.

Secondary Considerations

Further, with regard to Nicoli, as discussed in the Response filed on June 17, 2009, even if it were assumed arguendo that a *prima facie* case of obviousness has been established, secondary considerations, such as, unexpected results can overcome the *prima facie* case of obviousness. In this regard, Nicoli discusses carrier particles consisting of polystyrene latex, which are used to perform the assay in conjunction with gold particles. (Col. 15, lines 28-33). The present specification describes that when using gold particles only, the particle sizes of the gold particles can be differentiated with certainty. The present specification further provides that the use of polystyrene particles in conjunction with gold particles is not desirable because it is not possible to differentiate with certainty the particle sizes of both the gold particles and the polystyrene particles. (See, for example, page 66, lines 7-13 and page 67, lines 1-20). Thus, it has been unexpectedly found in the presently pending application that using gold particles and not a combination of gold particles and polystyrene particles, unexpectedly results in greater certainty in differentiating particle sizes. This is desirable because greater certainty in differentiating particle

sizes allows for improved assays. (See, for example, page 62, lines 20-33 and page 63, lines 1-15 of the present specification).

Further, the presently recited scattered light-detectable gold particles having a diameter of from about 40 nm to about 140 nm have unexpectedly desirable light scattering power compared to other materials such as polystyrene. (See, for example, pages 61-69 of the present specification). Moreover, the present specification shows that the relative scattering power of the presently recited gold particles unexpectedly increases exponentially from a diameter of about 40 nm to about 140 nm. (See, for example, Table 5 at page 66 of the present specification).

Thus, Nicoli either alone or in combination with any other cited reference not only fails to disclose or suggest gold particles having a diameter of from about 40 nm to about 140 nm and having less than a 5% coefficient of variation in size, as discussed hereinabove, Nicoli, either alone or in combination with any other cited reference, also fails to show the above-discussed unexpected advantages of the presently recited population of gold particles which excludes polystyrene particles.

In view of at least the above, the obviousness rejections should be withdrawn.

Conclusion

Applicants invite the Examiner to contact Applicants' representative at the telephone number listed below if any issues remain in this matter, or if a discussion regarding any portion of the application is desired by the Examiner.

In the event that this paper is not timely filed within the currently set shortened statutory period, Applicants respectfully petition for an appropriate extension of time.

The fees for such extension of time may be charged to our Deposit Account No. 02-4800.

In the event that any additional fees are due with this paper, please charge our Deposit Account No. 02-4800.

Respectfully submitted,

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